

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
CHARLOTTESVILLE DIVISION

CYNTHIA B. SCOTT, et al.,

Plaintiffs,

v.

HAROLD W. CLARKE, et al.,

Defendants.

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Case No. 3:12-cv-36

**DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' EMERGENCY MOTION
FOR ENFORCEMENT PURSUANT TO SETTLEMENT AGREEMENT**

Defendants Harold W. Clarke, A. David Robinson, Stephen Herrick, Eric Aldridge, and Dr. Paul Targonski (collectively "Defendants"), by counsel, submit this Response in Opposition to Plaintiffs' Emergency Motion, ECF No. 562. In support thereof, Defendants state as follows:

INTRODUCTION

On April 30, 2019, Plaintiff Margie Ryder filed an Emergency Motion "pursuant to § V.3 of the Settlement Agreement." ECF No. 562, at *1 (citing ECF No. 221-1 at 24). That section of the Settlement Agreement reads:

In the event of a medical emergency posing a **substantial threat of immediate harm** to any prisoner residing at FCCW, as identified by the Compliance Monitor or the Plaintiffs through counsel, the notice and 30-day cure provisions of this Settlement Agreement shall be deemed waived by the Defendant[,] and the Plaintiffs, through counsel, may seek immediate enforcement of its terms by the Court.

ECF No. 221-1, at *25 (emphasis added).¹

¹ Unless otherwise noted, pincites to ECF documents refer to the blue "Page [] of []" text in the document's footer.

There is no “medical emergency posing a **substantial threat of immediate harm**” to Ms. Ryder. Ms. Ryder’s Emergency Motion is nearly silent on the status of Ms. Ryder’s care at FCCW during the last 3 months from February 14, 2019 to the present. Instead, Ms. Ryder’s Emergency Motion focuses almost exclusively on alleged events from March 2018 through February 2019, with Declarations from providers who have had no contact with Ms. Ryder for at least three months, or even longer.

Notably, Ms. Ryder’s Emergency Motion makes no mention of (1) Ms. Ryder’s treatment at the VCU PAH Clinic on March 21, 2019 (as well as May 9, 2019, which was after Ms. Ryder’s Emergency Motion), or (2) FCCW Medical Director Dr. Paul Targonski’s ongoing coordination of Ms. Ryder’s care in coordination with her medical team at VCU in anticipation of her upcoming release from FCCW.

As discussed further herein, Ms. Ryder has presented no information or evidence to trigger Section V.3. of the Settlement Agreement, as Ms. Ryder offers no evidence that her current status of medical care at FCCW constitutes a “**substantial threat of immediate harm**” to Ms. Ryder.²

STATEMENT OF FACTS

I. Timeline of Relevant Events

The timeline of Ms. Ryder’s care is crucial to the issue before the Court: namely, whether there is currently a “substantial threat of immediate harm” to Ms. Ryder.

² The Defendants categorically reject any claim that Ms. Ryder’s care at FCCW has ever been deficient or insufficient. This pleading will, however, focus on the facts and claims relevant to the implication of Section V.3. of the Settlement Agreement and not the totality of Ms. Ryder’s care at FCCW.

A. March 2018–August 2018

Margie Ryder arrived at FCCW in March 2018. From her arrival at FCCW until August 2018, Ms. Ryder mixed her own medication. During this period in which Ms. Ryder mixed her own medication, she was hospitalized four times on (a) April 7, 2018; (b) April 14, 2018; (c) July 11, 2018; and (d) August 13, 2018.

In the summer of 2018, Dr. Thomas Gable, the FCCW Medical Director at that time, expressed his concerns to Dr. Nicholas Scharff, the Court’s Compliance Monitor, that Ms. Ryder “has been noted by nursing staff to be adjusting the rate of her infusion leading to some of her problems.” ECF 562-7. Dr. Gable also stated to Dr. Scharff in an email of July 16, 2018, that Ryder “draws the Remodulin out of the vial herself and then the nurse checks it. I believe she pushed too much air into the vial and damaged the seal last week causing it to leak.” ECF 562-8.

Upon Ms. Ryder’s return to FCCW following her August 2018 hospitalization, Ms. Ryder no longer mixed her own medication or observed the mixing of her medications. On August 25, 2018, Dr. Paul Targonski became the FCCW Medical Director. **Ex. A**, Targonski Decl., ¶ 7. Ms. Ryder’s Emergency Motion is essentially silent as to the six month period from Dr. Targonski’s arrival in late-August 2018 to February 2019. There were no medical emergencies regarding Ms. Ryder during this period.

B. Ms. Ryder’s February 11–14, 2019 UVA Hospitalization

Dr. Paul Targonski, FCCW’s Medical Director, addresses Ms. Ryder’s February 2019 hospitalization in his Declaration. The conclusion that there was a “mixing error” with

Ms. Ryder's Treprostinil³ by FCCW is conjectural. **Ex. A**, Targonski Decl., ¶ 9. Ms. Ryder's blood pressure was typical of her usual state, and she routinely has nausea, various aches and pains, flushing and vasodilation. There were no findings of cardiac abnormality at the University of Virginia emergency department to support a cardiac etiology of her chest pain. Id. at ¶ 9.

On either February 12 or 13, 2019, Dr. Targonski spoke via telephone with Dr. Jamie Kennedy at the University of Virginia concerning Ms. Ryder's continued care at FCCW. Id. at ¶ 11. During this telephone discussion and with the express purpose of obtaining evidence-based best practices to enhance training and performance at FCCW, Dr. Targonski asked Dr. Kennedy to share the University of Virginia's IV Treprostinil medication mixing and delivery processes and prostacyclin handling protocols. Id. at ¶ 11.

Despite the fact that Dr. Targonski is also on the UVA medical faculty/staff, Dr. Kennedy refused to provide the requested protocols. Id. at ¶ 11. Instead, Dr. Kennedy referred FCCW to Accredo, an outside home health agency. FCCW and Dr. Targonski arranged for Accredo to provide additional/supplemental training to the FCCW nursing staff on February 14, 2019. Id. at ¶ 11. Notwithstanding Dr. Targonski's professional analysis that there was no conclusive evidence that Ms. Ryder's perceived symptoms were the result of a mixing error of her Treprostinil by FCCW in February 2019, his primary focus as the FCCW Medical Director has been to minimize the probability of an adverse event happening at any point in her care or in the future, and to maximize the overall health of all patients at FCCW. Id. at ¶ 10.

³ Treprostinil is the generic name for Remodulin.

C. February 14, 2019 to Present

From Ms. Ryder's return to FCCW on February 14, 2019, to the present, Ms. Ryder's medical care has been exclusively handled by the FCCW staff and her VCU physicians. Since her February 2019 hospitalization at UVA, Ms. Ryder has been seen on two occasions by her VCU Pulmonary physicians: on March 21, 2019 and May 9, 2019. Id. at ¶ 15.

On March 21, 2019, Ms. Ryder was seen by Dr. Grinnan of the VCU PAH Clinic. The VCU records from this March 21, 2019 visit were provided to Dr. Targonski and document that Ms. Ryder reported that "[s]he is doing generally well today and is happy with her improvement." This note from VCU is consistent with Dr. Targonski's interactions with Ms. Ryder since her return from UVA in February 2019. Ms. Ryder was again seen by Dr. Grinnan at VCU on May 9, 2019. VCU's records from this visit reflect that "she is doing generally well today." Id. at ¶ 15. Notably, these two VCU Pulmonary Critical Care records contain no mention of any need to alter the manner of delivery of care by FCCW.

Since Ms. Ryder's return to FCCW on February 14, 2019, Dr. Targonski has spoken with her regularly, and Dr. Targonski has been actively monitoring Ms. Ryder's medical condition. Under Dr. Targonski's direction as FCCW Medical Director, care processes in the infirmary have been reinforced with respect to routine processes for lab surveillance, medication ordering reviews, patient assessments, team rounding, care coordination, dismissal planning and patient engagement. Additionally, yoga and other activities have been initiated in the infirmary to enhance wellness for all infirmary patients, including Ms. Ryder. Id. at ¶ 12.

Since Ms. Ryder's return to FCCW from UVA on February 14, 2019, none of the UVA-affiliated physicians who executed Declarations in connection with Ms. Ryder's Motion for Emergency Enforcement have contacted Dr. Targonski to discuss any concerns with the quality of Ms. Ryder's care at FCCW. In fact, apart from Dr. Targonski's discussion with Dr. Kennedy during Ms. Ryder's February 2019 hospitalization, he has not had any contact with any other UVA-affiliated physician about Ms. Ryder. Id. at ¶ 13.

Dr. Targonski received the letters from Plaintiffs' counsel of February 22, 2019 and March 15, 2019, both of which are attached as exhibits to Plaintiffs' Motion for Emergency Enforcement. Upon receipt of both of these letters, Dr. Targonski again reviewed the totality of Ms. Ryder's medical care at FCCW. In an effort to provide Plaintiffs' counsel with a comprehensive report of her medical care at FCCW, Dr. Targonski personally prepared the report, dated March 22, 2019, which is attached as Exhibit 16 to Plaintiffs' Motion for Emergency Enforcement. Id. at ¶ 14.

Following the transmission of his March 22, 2019 report to Plaintiffs' counsel, Dr. Targonski did not receive any communication from Plaintiffs' attorneys or any of Ms. Ryder's other health care providers (including her UVA-affiliated physicians and nurses who executed Declarations in connection with Plaintiffs' Emergency Motion) expressing any concern with the quality of care that Ms. Ryder was receiving at FCCW. Id. at ¶ 14.

While above what is required for the proper administration of her medication, beginning May 1, 2019, the Treprostinil cartridges for Ms. Ryder have been, and will continue to be, premixed by the IV team at Diamond Pharmacy. Ms. Ryder's Treprostinil is now obtained via the FCCW pharmacy supplier in pre-mixed cartridges and a back-up

supply of cartridges and Treprostinil and Diluent in unmixed form is maintained should the need arise. A routine reorder process has also been implemented. Id. at ¶ 16.

Dr. Targonski is also actively addressing Ms. Ryder's care continuity as she approaches her release date. Dr. Targonski has proactively been in contact with Ms. Ryder's VCU team to ensure the best transition of care after she leaves FCCW. He has confirmed with Ms. Ryder her intent to continue her care at VCU, rather than Johns Hopkins where she had been cared for previously, and he has conveyed Ms. Ryder's wishes to the VCU team. Dr. Targonski also requested early initiation and confirmation of Medicaid coverage for Ms. Ryder to reduce risk associated with inadequate or no insurance affecting her medical access or medications. Ms. Ryder has expressed to Dr. Targonski that she is appreciative of his efforts to engage VCU to ensure the coordination of her care when she leaves FCCW. Id. at ¶ 17.

II. DECLARATION OF DR. TARGONSKI, MD, PHD, MPH

A. Information About the Delivery of Treprostinil

As explained further in Dr. Targonski's Declaration, he understands that Ms. Ryder believes that she experienced subjective symptoms that she attributes to "FCCW mixed my medication incorrectly, overdosing me on Remodulin," as stated in Ms. Ryder's Declaration. **Ex. A**, Targonski Decl., ¶ 18. In his role as her physician, Dr. Targonski does not minimize or disregard a patient's sincerely held beliefs about their bodies, experiences or their medical care. Id. at ¶ 18. However, pulmonary arterial hypertension is a complicated condition capable of myriad presentations for a variety of reasons, and any expression of symptoms is not necessarily due to pulmonary arterial hypertension or Treprostinil side effects. Id. at ¶ 18.

In her Declaration, Ms. Ryder reported symptoms of “chest pain, nausea, vomiting, and skin discoloration” and “body pain.” It is not uncommon for patients with PAH to report these symptoms even in the absence of a serious adverse event. Id. at ¶ 19. Indeed, Ms. Ryder and many other patients with and without PAH commonly experience these symptoms. Id. at ¶ 19. This statement is not meant in any way to trivialize these symptoms; rather, it is to provide data presenting a balanced view that these symptoms are relatively common among persons with PAH and those with PAH using Treprostinil, and may not necessarily be attributable to a iatrogenic serious adverse event. Id. at ¶ 19.

Ms. Ryder’s experience at FCCW since August 2018, even if she experienced a care-related symptomatic event, is not statistically different than that experienced by PAH patients monitored very closely and by systematic assessments in clinical trials. Id. at ¶ 20. And it is unclear that her symptoms were attributable to a medication error in the absence of objective evidence or corroborating objective findings given the commonality of such symptoms in this malignant disease. Id. at ¶ 20.

B. Ms. Ryder’s Request to Observe the Mixing of Treprostinil

Dr. Targonski was personally familiar with Ms. Ryder’s request that she be permitted to observe the mixing of her Treprostinil. **Ex. A**, Targonski Decl., ¶ 21. As noted above, beginning May 1, 2019, the Treprostinil cartridges for Ms. Ryder have been, and will continue to be, premixed by the IV team at Diamond Pharmacy. Id. at ¶ 21. Dr. Targonski spoke with Dr. Jamie Kennedy during Ms. Ryder’s February 2019 hospitalization about this issue. Id. at ¶ 22. As Dr. Targonski discussed with Dr. Kennedy during their telephone call on this topic, the established medical literature and his own personal experience as a physician do not support the conclusion that a patient’s

observation of the mixing of medications assures that errors in mixing will not occur. Id. at ¶ 22. Dr. Targonski explained to Dr. Kennedy that her suggestion that Ms. Ryder be able to watch the nurses mix her medication as a means of reducing the probability of medication errors is not supported by medical literature. Id. at ¶ 22.

It is notable that Ms. Ryder's increased frequency of objective symptoms and hospitalizations occurred during the period in which she was observing and participating in her medication mixing and management most closely. Id. at ¶ 23. Since August 2018, the event rate has reduced to that experienced by well-cared for patients. Id. at ¶ 23. It is Dr. Targonski's professional medical opinion that the totality of Ms. Ryder's medical history supports the conclusion that her participation in medication management was associated with a frequency of adverse events more consistent with a greater threat to her health. Id. at ¶ 23.

Of course, it is not unusual for physicians, including professional colleagues within the University of Virginia medical community, to have a good-faith disagreement and dialog about the best course of treatment for a patient, as Dr. Targonski did with Dr. Kennedy on this issue. Dr. Targonski respectfully disagreed with Dr. Kennedy's position on this issue based upon the totality of his medical education and experience, and his knowledge of Ms. Ryder's medical condition. Id. at ¶ 24.

C. Misunderstanding Regarding the Relevance of "Bubbles"

Paragraph 6 of Margie Ryder's Declaration reflects a misunderstanding regarding the relevance of "bubbles." **Ex. A**, Targonski Decl., ¶ 25. Of note, Ms. Ryder has a 100 ml cartridge inserted every 48 hours, and it runs at a rate of 38 ml/day in her pump. Id. at ¶ 25. Since the medication is advised to not be used for more than 48 hours once the

cartridge is punctured, Ms. Ryder's cartridge is changed every 48 hours, after 76 ml have been expended (38 ml/day for 2 days), leaving 24 ml remaining in each cartridge. Id. at ¶ 25. This volume is wasted rather than varying the time of day at which a cartridge is normally changed, which would complicate routinization of practice and possibly induce a risk of error. This is the standard of care, and FCCW adheres to this standard. Id. at ¶ 25.

Additionally, Ms. Ryder's pump—the CADD Legacy-1 Model 6400—is equipped with an air bubble detection alarm. Id. at ¶ 26.

III. DECLARATION OF ELLEN KATZMAN, BSN, RN

The following additional facts are contained in the Declaration of Ellen Katzman, BSN, RN, who has been employed at FCCW as a registered nurse since January 2018 and served as the FCCW Nurse Administrator since June 2018. **Ex. C**, Katzman Decl., ¶ 1.

In 2018 prior to Margie Ryder's arrival at FCCW, the FCCW nursing staff had training with Julia Watson of Accredo on the administration of Ms. Ryder's medications for her diagnosis of PAH. Id. at ¶ 6. This training included the proper administration of Remodulin. Id. Ms. Watson of Accredo provided additional training to the FCCW nursing staff in February 2019. Id. Every nurse who has been involved in the administration of Ms. Ryder's Remodulin since her return from UVA in February 2019 has been formally trained in this process. Id.

The FCCW nurses are trained by the FCCW nursing management staff prior to administering any medication the first time. Id. at ¶ 7. With regard to the administration of Remodulin, prior to FCCW's recent acquisition of pre-mixed cassettes, FCCW nursing management oversaw the setting up of the cassette. Id. Additionally, FCCW nurses initiated Remodulin therapy in groups of two to ensure accuracy and minimize issues. Id.

Ms. Ryder's required medication and medical supplies are consistently ordered to ensure an appropriate supply. Id. at ¶ 8. FCCW maintains a back-up vial of Remodulin readily available. Id. FCCW also maintains an infusion guidebook, illustrating the medication set-up in a step-by-step fashion, as well as a PAH pamphlet for continued education and knowledge in relation to this life-threatening condition. Id. Since Ms. Ryder's return from UVA in February 2019, Ms. Katzman is not aware of any issues or concerns with the quality of the nursing care provided by the FCCW nursing staff. Id. at ¶ 9. Ms. Ryder has not raised any concerns with Ms. Katzman personally. Id. Ms. Katzman rounds at a minimum of once a week through the entire facility. Id. Ms. Katzman has regularly interacted with Ms. Ryder since her return from UVA in February 2019, and she has not raised any concerns or issues with Ms. Katzman. Id.

IV. DECLARATION OF FCCW WARDEN ERIC ALDRIDGE

The following additional facts are contained in the Declaration of FCCW Warden Eric Aldridge.

According to VDOC's records, Ms. Ryder submitted one (1) Informal Complaint since January 1, 2019. **Ex. B**, Aldridge Decl., ¶ 5. On April 1, 2019, Ms. Ryder submitted an Informal Complaint regarding not receiving her "9PM meds for 3/31/19 until 1AM on 4/1/19." Id. That Informal Complaint was received by the FCCW Grievance Coordinator on April 3, 2019. Id. FCCW staff responded to Ms. Ryder's Informal Complaint on April 9, 2019. Id.

Ms. Ryder has not submitted any regular grievances or emergency grievances since January 1, 2019. Id. at ¶ 6. As part of Warden Aldridge's regular duties as Warden of FCCW, he usually conducts weekly rounds of FCCW in order to engage with offenders and

staff and evaluate operations at FCCW. Id. at ¶ 7. As part of his weekly rounds of FCCW, he often visits the housing unit where Ms. Ryder is housed, H Wing in Building 2. Id. at ¶ 8. He often visits Building 2 during his weekly rounds because it is a medical suite. Id. at ¶ 9. During his rounds of the offenders' housing units and the medical department, it is common for offenders to approach Warden Aldridge directly regarding any concerns they might have. Id. at ¶ 10.

According to FCCW's administrative logs, since January 1, 2019, Warden Aldridge has visited Ms. Ryder's housing unit no less than twelve (12) times. Id. at ¶ 11. As he does not always sign the log book when he enters the housing unit, it is possible he has visited Ms. Ryder's housing unit more than twelve times since January 1, 2019. Id. During Warden Aldridge's visits to Ms. Ryder's housing unit he has seen Ms. Ryder and exchanged pleasantries with her. Id. at ¶ 12. During none of Warden Aldridge's visits to Ms. Ryder's housing unit has Ms. Ryder approached him to advise of any concerns regarding her medical care, staff handling of her informal complaints or grievances, conditions at FCCW, or any other concerns for that matter. Id. at ¶ 13.

Warden Aldridge has also reviewed FCCW's logs for off-site medical appointments. Ms. Ryder has not had any appointments or visits to the University of Virginia Health System since her hospitalization in February 2019. Id. at ¶ 14.

ARGUMENT & AUTHORITY

I. There is No Substantial Threat of Immediate Harm to Margie Ryder.

The sole question before this Court on Ms. Ryder's Emergency Motion pursuant to Section V.3. of the Settlement Agreement is whether there currently exists a "medical emergency posing a **substantial threat of immediate harm**" to Ms. Ryder. In order to

trigger the application of this provision, Plaintiff must present evidence that Ms. Ryder is currently facing a medical emergency posing a substantial threat of immediate harm.

Plaintiff's Motion contains no such evidence. Instead, Plaintiff's Motion is premised almost entirely on alleged events from 2018 and February 2019. In fact, Plaintiff's Motion is silent both as to her care between August 2018 and February 2019 and her care for the past three months, and fails to inform the Court that Ms. Ryder was seen by her VCU PAH physicians on March 21, 2019 (and again on May 9, 2019).

For the past three months from February 14, 2019 to the present, Ms. Ryder has been exclusively under the care of the FCCW medical/nursing staff and the VCU Pulmonary Critical Care physicians. While the UVA physicians and nurse have taken the time to execute Declarations in March and April 2019, the representations by these UVA clinicians as contained in Ryder's Emergency Motion is limited to events from 2018 and February 2019.

Ms. Ryder is currently under the care of Dr. Paul Targonski at FCCW; and she has offered no information that Ms. Ryder's physicians from the VCU Pulmonary Critical Care team (the only other physicians that she has seen in the past three months) have expressed any concern about the quality of care she is currently receiving at FCCW.

The timing of Ryder' Emergency Motion also belies the alleged "threat of immediate harm." Section V.3 of the Settlement Agreement expressly provides that the notice and cure provisions of the Settlement Agreement do not apply in the event "of a medical emergency posing a substantial threat of immediate harm" ECF No. 221-1, at *25. Yet, rather than filing the instant motion in April 2018, June 2018, July 2018, August 2018, any time between August 2018 and February 2019, or even in February 2019, Ryder

essentially utilized the Settlement Agreement's notice and cure process. The delay in the filing of this motion contraindicates the existence of a "medical emergency posing a substantial threat of immediate harm."

II. Ms. Ryder's Complaints Are Insufficient to Trigger § V.3 of the Settlement Agreement.

Ms. Ryder's Emergency Motion contains two complaints about her care at FCCW over the past three months from February 14, 2019 (when she returned from her final hospitalization) to the present. First, Ms. Ryder complains that she has not been permitted to watch the mixing of her Treprostinil. Second, Ms. Ryder alleges that "as recently as April 9, an FCCW nurse has tried to use a cartridge that had a large air bubbles in it." ECF 562-3.

Ms. Ryder's request that she be permitted to observe the mixing of her medication is moot. Beginning May 1, 2019, Ms. Ryder's Treprostinil cartridges have been (and will continue to be) premixed by the IV team at Diamond Pharmacy. Accordingly, Ms. Ryder's request to observe the FCCW nursing staff mix her medications is moot.⁴

With regard to Ms. Ryder's concern about "bubbles" in her cartridge, Dr. Targonski addresses this issue in his Declaration to explain that Ms. Ryder's concerns are not well grounded and do not trigger Section V.3 of the Settlement Agreement.

III. Anticipated Testimony from the UVA Physicians and Nurse is Not Relevant or Admissible.

Plaintiffs intend to call various physicians who cared for Ms. Ryder in 2018 and February 2019 to testify at the hearing on Plaintiffs' Emergency Motion. These physicians lack any current knowledge of Ms. Ryder's condition as Ms. Ryder's last visit to UVA was in

⁴ One of Ms. Ryder's requests in her Emergency Motion is that Defendants be ordered to "begin using pre-mixed Remodulin for Ms. Ryder"

February 2019. As this is ostensibly an emergency motion regarding a threat of “immediate” harm, testimony regarding Ms. Ryder’s hospitalizations in 2018 or February 2019 hardly seems relevant. Rather, Ms. Ryder’s most recent treatment in May 2019 has been coordinated with her care team at VCU who, coincidentally, Plaintiffs have not subpoenaed to testify. Further, the Declaration of UVA Doctors and Declaration of Lauren Bedard, RN (UVA) do not address Ms. Ryder’s current status and thus are irrelevant to the Motion before the Court.

Additionally, any testimony from Nurse Lauren Bedard that implicates medical causation issues is inadmissible, as she is not properly qualified to opine on such matters. The Defendants further move to strike Nurse Bedard’s Declaration on these grounds.

CONCLUSION

For the above stated reasons, and pursuant to any evidence and argument presented at the May 22, 2019 hearing, the Defendants respectfully request that the Court deny Plaintiff's Emergency Motion and grant further relief as the Court deems appropriate.

Respectfully Submitted,

HAROLD W. CLARKE, A. DAVID ROBINSON,
STEPHEN HERRICK, ERIC ALDRIDGE, AND
PAUL TARGONSKI, M.D.

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CERTIFICATE OF SERVICE

I hereby certify that on May 14, 2019 I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will automatically send notification of such filing to all counsel of record.

/s/ _____
Of Counsel

